Citation:

Sullivan DH, Morley JE, Johnson LE, Barber A, Olson JS, Stevens MR, Yamashita BD, Reinhart SP, Trotter JP, Olave XE. The GAIN (Geriatric Anorexia Nutrition) Registry: The impact of appetite and weight on mortality in a long-term care population.*J Nutrition Health and Aging.* 2002; 6 (4): 275-281.

PubMed ID: 12486448

Study Design:

Prospective cohort study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine if any baseline nutrition or health status indicators of high-risk residents correlated with subsequent weight gain or improvement in appetite and whether weight loss during the six-month observation period correlated with higher mortality after controlling for baseline characteristics.

Inclusion Criteria:

- Live in one of the 96 long-term care facilities recruited for study
- Have one of the following documented in the medical record within the prior three months:
  - Poor appetite (leaves 25% of food uneaten at most meals)
  - Documentation of poor appetite prompting dietary consult
  - Weight loss of 5% or greater within a one-month period
  - Documentation of weight loss prompting dietary consultation.
- Be one of 20 randomly selected residents meeting the inclusion criteria in each facility.

Exclusion Criteria:

None stated.

Description of Study Protocol:

- *Recruitment:* Study entry was limited to a stratified random sample of subjects. From the list of residents who met study criteria, up to a maximum of 20 were chosen at random for study entry from each facility.
- *Design:* Prospective cohort study; the GAIN registry. Baseline chart review and monthly

follow-up for six months.
- *Blinding used:* All data collected from the resident's medical record were blinded and coded in a manner that maintained strict patient and facility confidentiality
- *Intervention:* None.

Statistical Analysis

- The relationship between appetite improvement (as the outcome) was analyzed using student's T-test or chi-square. Independent variables associated significantly with outcome ($P<0.05$) were included in stepwise logistic regression.
- The relationship between weight gain (as the outcome) and baseline variables was analyzed similarly
- Time to death or last follow-up was analyzed using Cox Proportional-Hazards Regression Analysis with covariant analysis for confounders impacting mortality.

Data Collection Summary:

Timing of Measurements

Baseline and monthly for six months.

Dependent Variables

- Survival
- Weight gain (5% over six months)
- Appetite (improvement of one point on a three-point rating scale).

Independent Variables

- Supplements (commercial polymeric products, facility prepared items, total and peripheral parenteral nutrition and vitamins)
- Orexigenics (drugs prescribed for nutrition purposes).

Control Variables

- Demographic data
- Diagnoses and pressure sores.

Description of Actual Data Sample:

- *Initial N:* 1,000 subjects from 96 long-term care facilities
- *Attrition (final N):* 894; 76 were lost to follow-up and 30 had incomplete data sets
- *Age:* 86±8.0 years (range of 65 to 104)

Other Relevant Demographics

- 77% female
- 36% with full dentures
- 32% with pressure sores
- 12% taking orexigenics
- 78% taking supplements
- *Mean number of diagnoses:* 7.0±3.0 (range, one to 18)

- *Mean number of medications:* 10±5 (range, one to 25)
- *Mean years length of stay in facility prior to study:* 2±3 (range, zero to 21).

Anthropometrics

- *Mean weight:* 55±12kg (range, 28 to 103)
- *Mean BMI:* 21.1±4.2kg/m^2 (range, 10.3 to 37.5)
- *Location:* Eight states (Ohio, Oregon, Pennsylvania, Florida, New York, Maryland, California and Washington).

Summary of Results:

	Improved Appetite		P-Value
	Yes	*No*	
Age	84.6±8.3	86.5±7.9	0.022
BMI	21.5±4.0	20.9±4.2	0.043
Poor Appetite	59.1%	30.6%	<0.001

	Weight Gain		P-Value
	Yes	*No*	
Age	84.5±8.7	86.4±7.8	0.006
BMI	19.9±3.8	21.4±4.2	<0.001
Diagnosis of COPD	17.4%	11.5%	0.034
Feeding Dependence	13.0%	19.5%	0.044
Receiving Orexigenics	16.9%	10.7%	0.022

	Mortality		P-Value
	Yes	*No*	
Age	88.4±7.1	85.4±8.1	<0.001
BMI	19.9±4.3	21.3±4.1	<0.001
Number of Diagnoses	6.5±3.3	6.1±2.3	0.037
Number of Medications	6.5±3.3	5.8±3.2	0.16
Diagnosis of CHF	32.8%	21.6%	0.002
Feeding Dependence	23.3%	16.8%	0.044
Feeding Independence	12.2%	22.1%	0.003
Poor Appetite	51.1%	34.5%	<0.001
Presence of Pressure Sores	31.7%	19.2%	<0.001
Weight Loss**	65.0%	46.7%	<0.001

Diagnosis of COPD	18.7%	11.7%	0.049

Other Findings

- During the six-month study, younger age was the strongest correlate of appetite improvement
- The odds of gaining weight were negatively correlated with BMI, age and feeding dependency
- Subjects who were receiving appetite stimulants (orexigenics) at study entry had a 70% greater probability of gaining weight than those who were not
- A weight loss during the six-month period was associated with a nearly two-fold increase in the likelihood of dying (adjusted RR, 1.95; 95% confidence interval, 1.43 to 2.66)
- Predictors of weight a 5% or greater weight gain within six months included BMI (adjusted odds ratio; 95% CI of 0.89; 0.85 to 0.93), age (adjusted odds ratio; 95% CI of 0.96; 0.94 to 0.98), feeding dependency (adjusted odds ratio; 95% CI of 0.55; 0.34 to 0.89) and receiving appetite stimulants (adjusted odds ratio; 95% CI of 1.70; 1.06 to 2.72)
- Continued weight loss appeared to have ominous implications for mortality.

Author Conclusion:

- The course of nutritional problems within nursing homes is highly variable. Continued weight loss, however appears to have ominous implications for mortality.
- Younger residents who are not dependent on others for feeding assistance and who receive orexigenics tend to experience weight gain.

Reviewer Comments:

- *Study participants were compared with national data and suffered significantly more dementia and depression. They also received significantly more antidepressants, had almost four times more pressure ulcers and experienced six times the unplanned weight loss of the national average for nursing homes. Therefore, findings may not apply in other long-term care populations.*
- *Authors note that they were not able to directly validate the accuracy of the weights recorded for each subject.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes

4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes

4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A

7.	**Were outcomes clearly defined and the measurements valid and reliable?**		No
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	No
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		???
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes